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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,584	03/12/2001	Matthew L. Albert	600-1-276 CIP	5033

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[REDACTED] EXAMINER

CANELLA, KAREN A

[REDACTED] ART UNIT  
1642 PAPER NUMBER

DATE MAILED: 08/20/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

## ***Office Action Summary***

<b>Application No.</b>	<b>Applicant(s)</b>	
09/804,584	ALBERT ET AL.	
<b>Examiner</b>	<b>Art Unit</b>	
Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on \_\_\_\_\_.  
2a)  This action is **FINAL**.                    2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-41 is/are pending in the application.  
4a) Of the above claim(s) 4-18, 20 and 23-41 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-3, 19, 21 and 22 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.  
4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

**DETAILED ACTION.**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The objection to the disclosure and the specification is withdrawn in light of applicants corrected declaration. Because of this amendment applicant is claiming a priority date which renders the rejections under the prior art moot. Accordingly, an additional species I (a) the method wherein the absence of effective CD+4 T cell help is attained by exclusion of CD+4 T-cells and the species of II (a), tumor antigens, will be examined to the extend that they read of the species of I(a) and II(a)..

The rejection of claims 1, 2, 4, 16-19, 21 and 22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicants amendments.

Claims 1-41 are pending. Claims 1, 17, 19 and 21 have been amended. Claims 23-41, drawn to non-elected inventions are withdrawn from consideration. Claims 1, 2, 4, 15-19, 21 and 22, drawn in part to the species of I ((d) a method wherein the absence of effective CD+4 T-cell help is attained by inhibiting signaling consequence to dendritic cell T-cell engagement and species II (b) viral antigens, are withdrawn from consideration to the extend that they read on the species I(d) and II (b). Claims 1, 2, 3, 19, 21 and 22 are examined on the merits to the extend that they read of the species of I(a) and II(a)..

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 3, 19, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

The first paragraph of 35 U.S.C. 112 states that "the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ (CCPA 1977)). Additionally the courts have determined that "...where a statement is , on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factor are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The instant invention is drawn to a method for inducing tolerance to a tumor antigen in a mammal. The art teaches that many patients have tolerance to their own tumor antigens and that this prevents the patients immune response from effectively acting against their tumors (for example, Matsui et al, Journal of Immunology, 1999, Vol. 163, pp. 184-193, Ada, Immunology and Cell Biology, 1999, Vol. 77, pp. 180-185, Becker et al, International Immunology, 1993, Vol. 5, pp. 1501-1508). The art teaches that it is desirable to break this tolerance to allow for an anti-tumor immune response (the abstract of Spooner et al, International Journal of Oncology, 1995, Vol. 6, pp. 1203-1208, the abstract of Sotomayor et al, Critical Reviews in Oncogenesis, 1996, Vol. 7, pp. 433-456 and the abstract of Pandha et al, Drugs of the Future, 1997, vol. 22, pp. 747-756). Although it was known in the art that the activation of antigen specific CD+8 T-cells by dendritic cells requires the activity of CD+4 T-cells (Bennett et al (Journal of Experimental Medicine, 1997, Vol. 186, pp. 65-70), there are no teachings in the art or in the specification on benefits of inducing apoptosis in tumor specific CD+8 T cells. The specification does not teach how one of skill in the art would use the instant method as it would eliminate tumor specific CD+8 T-cells capable of destroying tumor cells which would not result in a therapeutic response.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella

Karen A. Canella, Ph.D.  
Patent Examiner, Group 1642  
8/11/03